DEPARTMENT OF HEALTH & HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services
Center for Substance Abuse Prevention
Center for Substance Abuse Treatment
Rockville MD 20857

DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION
DRUG TESTING ADVISORY BOARD

JUNE 8 - 9, 2004

The Drug Testing Advisory Board was convened for its meeting at 8:30 A.M. on June 8, 2004, at the Residence Inn, 7335 Wisconsin Ave., Bethesda, Maryland.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on June 8 from 8:30 A.M. to 11:30 A.M. The meeting was closed to the public on June 8 from 11:30 A.M. until adjournment on June 9 at noon for review, discussion, and evaluation of proprietary information regarding the drug testing laboratories and to discuss and evaluate public comments submitted on the Department's proposed changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Board members present:

Robert Stephenson II, Chairman
Dr. George Jackson
Dr. William Ferguson Reid
Dr. Matt Slawson
Dr. Sue Brown
Dr. Paula Childs
Dr. Mahmoud ElSohly
Dr. Tai Kwong
Dr. Fred Fochtman
Dr. Michael Smith

Executive Secretary present:

Dr. Donna Bush, Division of Workplace Programs (DWP), CSAP

Others present for all or a portion of the meeting were:

Dr. Walter Vogl, DWP, CSAP
Charles LoDico, DWP, CSAP
Dr. John Mitchell, RTI International
Dr. Mike Baylor, RTI International

Dr. Craig Sutheimer, RTI International
Jim Swart, Department of Transportation (DOT)
John Bobo, DOT
Dr. Yale Caplan, DOT Consultant
Dr. Garmon West, Nuclear Regulatory Commission (NRC)
Tim McCune, NRC
Dr. Alberto Gutierrez, Food and Drug Administration

TOPICS DISCUSSED IN OPEN SESSION

Note: The complete transcript of the open session is available on the Internet at: http://workplace.samhsa.gov

HHS UPDATE

Mr. Stephenson welcomed all DTAB members and public attendees to the meeting.

Dr. Bush stated that HHS published two important notices in the **Federal Register** on April 13, 2004. The first notice is the Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs. This notice contains new policies for conducting specimen validity tests on urine specimens. It is a final notice of revisions, but allows public comment on the less than 2 milligram/deciliter creatinine concentration cutoff criterion that was established to report a urine specimen as substituted as long as the specific gravity was less than or equal to 1.0010 or greater than or equal to 1.0200. The public comment period for this notice ends June 14, 2004. The second notice is the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs. This notice is proposing to establish scientific and technical guidelines for the testing of alternative specimens (such as hair, oral fluid, and sweat) in addition to urine specimen and to allow onsite testing. The public comment period for this notice ends July 12, 2004.

DOT UPDATE

Mr. Swart stated that John Bobo is the new director of the Office of Drug and Alcohol Policy and Compliance (ODAPC) at DOT, but could not attend to open session due to a prior commitment.

Mr. Swart reported that last fall DOT published a new management information form. The form combined 21 different multiple pages into one form that will be used by all the industries regulated by the six modes of transportation within DOT.

Additionally, DOT is preparing a notice of proposed rulemaking to parallel HHS's specimen validity testing final rule. The intent is to finalize the rule published in May 2003.

NRC UPDATE

Dr. West stated that the NRC is prepared to issue a proposed rule for its 10 CFR Part 26 by December 2005. He indicated that there would be a stakeholder meeting on July 7 - 8 in the Rockville, Maryland, area. At this meeting, NRC intends to roll out its own website in addition to discussion about 10 CFR Part 26.

Mr. McClune will be the primary NRC representative at future DTAB meetings.

REVISED MANDATORY GUIDELINES

Dr. Vogl gave a PowerPoint presentation on the Revised Mandatory Guidelines. He highlighted the major changes related to the new specimen validity testing policies and other coincidental changes that incorporate policies from other National Laboratory Certification Program documents.

PROPOSED REVISED MANDATORY GUIDELINES

Dr. Bush gave a PowerPoint presentation on the Proposed Revised Mandatory Guidelines. She discussed all the proposed policies on testing alternative specimens and conducting onsite testing. Dr. Bush encouraged all attendees to submit public comments to ensure that their opinions were properly documented.

ALTERNATIVE SPECIMEN PILOT PROGRAM

Dr. Mitchell gave a PowerPoint presentation on data from the pilot performance testing (PT) program for alternative specimens. Dr. Mitchell focused attention on the results from cycles 5, 6, and 7 for hair testing and cycles 4, 5, and 6 for oral fluid testing. Five laboratories participated in the analyzing the hair samples and 12 laboratories participated in analyzing the oral fluid samples.

Currently, the results of the hair pilot PT program suggest the following: it should include liquid samples for external control to assess laboratory standards because calibration issues within laboratories were identified by this process; poor recovery of analytes from hair matrix appears to be an issue for most participants (labs must adopt methods that are proven to maximize

recovery); and the proposed confirmatory cutoff concentration for THCA appeared to be beyond the sensitivity of most labs at this time. The results of the oral fluids pilot PT program suggest the following: PT materials containing opiates and THC need to be improved either by production of samples immediately preceeding the PT cycle or stabilizing the analytes; labs need to continue development of methodologies for the analysis of MDMA, MDA, and MDEA; and for all other analytes, many labs appeared to have reasonable sensitivity and accuracy.

PUBLIC COMMENTS

Ms. N.B. Varlotta was the only public attendee to make a public comment. Her specific comments are included in the transcript of the open session that is on the DWP workplace website.

The open session ended at 11:30 A.M.

TOPICS DISCUSSED IN CLOSED SESSION

The Board discussed a number of issues having a direct impact on the National Laboratory Certification Program after the November 1, 2004, implementation date for the revised Mandatory Guidelines. The issues included: the concentration and substances used for the PT program, revised checklist for evaluating laboratories, and accuracy and precision data of 4-decimal place refractometers.

The Board reviewed the performance data available for Point of Collection Test (POCT) devices, reviewed the FDA's role in clearing these devices, and evaluated the proposed policy for using these devices in the Federal program.

RTI International staff presented a number of specific laboratory issues and the Board discussed different solutions.

RTI International staff raised specific findings regarding corporate laboratory information management systems (LIMS) inspections.

There was a discussion of several issues raised by a number of public comments submitted for the proposed revisions to the Mandatory Guidelines.

Adulteration and substitution products available on the Internet to suborn drug testing programs were identified and recommendations were made for ways to minimize the impact these products could have on the Federal drug testing program.

ADJOURNMENT

The meeting adjourned at Noon on June 9.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Donna M. Bush

Donna M. Bush, Ph.D., D-ABFT
Executive Secretary
Drug Testing Advisory Board

Robert L. Stephenson

Robert L. Stephenson II, M.P.H.
Chairman
Drug Testing Advisory Board

These minutes will be formally considered by the Board at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.